S.C. Johnson (SCJ) Current and Historical Perspective

- **For over 10 years, S.C. Johnson has spearheaded efforts to reduce the use of animals in the hazard assessment process and has frequently used alternative irritancy assays for product development and labeling decisions.**
- **S.C. Johnson currently utilizes the BCOP assay in a weight-of-evidence approach for hazard classification and labeling purposes for non-registered products.**
- **S.C. Johnson has used this assay in a benchmark-related approach for over a decade in assessing a variety of product types (air fresheners, cleaning products, insecticides, and repellents etc).**
- **By combining in-house historical data from similar products, toxicology information on raw materials, and post-market surveillance, we are comfortable using BCOP alone, without in-vivo testing for non-registered products.**
- **The BCOP assay is an indispensable tool for assessing the potential irritancy of our products at S. C. Johnson.**

Conducting BCOP

- SCJ always conducts the BCOP using a standard protocol with concurrent benchmarks, controls and histology, if needed.
- Exposure and post-exposure times are chosen to be appropriate for the formula/chemical class of the test material.
- Each formula is carefully matched with a specific benchmark material for which the irritancy potential is well understood.
- Histology would be conducted on both the test sample and the benchmark for a complete assessment of degree and depth of injury.
- Histology is typically used in the following situations:
  - To understand new chemistries/formulas
  - To investigate known chemistries with delayed effects (e.g reactive chemicals), with chemicals where the mode of action is not easily predicted, or where complete picture is needed.
  - To further characterize damage identified by the standard BCOP endpoints.
  - To resolve borderline cases.

Evaluation of Data from BCOP

- **S. C. Johnson evaluates BCOP data using a comparative approach that we believe is more reliable for our product types rather than the classification system described by Sina et al, (1995) for pharmaceutical intermediates.**
- **S.C. Johnson always utilizes appropriate concurrent benchmark materials of previously well-defined materials toxicity and similar chemistry to the test to evaluate new formulations.**
- **Histology is an increasingly important endpoint for us because we believe that depth of injury as seen in histological evaluation is a good predictor of degree and duration of injury as described by Maurer et al. (2002).**

Conclusions

- **We appreciate the enormous effort that has gone into the production of the BRD and review of the data for the support of this assay.**
- **SCJ has submitted 5 data sets for this evaluation as we are very supportive of this effort.**
- **We respectfully request that our comments be carefully considered due to the wealth of investigation of the process, methodology, and its application by SCJ. The BCOP assay is an integral part in our product evaluation process as it has been for the past 10 years.**
- **We strongly believe that we have enough knowledge and experience with our formulations and this assay to make scientifically credible decisions regarding the categorization and labeling of our products.**